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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/068,134	02/06/2002	Rosana Kapeller-Libermann	35800/243653(5800-38A)	8517

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EXAMINER	
TUNGATURTHI, PARITHOSH K	
ART UNIT	**PAPER NUMBER**
1642	

DATE MAILED: 05/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/068,134	KAPELLER-LIBERMANN ET AL.	
	Examiner	Art Unit	
	Parithosh K. Tungaturthi	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-22 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-22 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-7, 12 and 18 drawn to an isolated nucleic acid, a host cell, a method of producing a polypeptide and a kit, classified in class 536, subclass 32.1 and class 435, subclasses 325+, 70.1+.

II. Claims 8-10 drawn to an isolated polypeptide and a kit, classified in class 530, subclass 300+.

III. Claim 11 and 15, drawn to an antibody, classified in class 530, subclass 387.1.

IV. Claims 13 and 14 drawn to a method of detecting the presence of a polypeptide, classified in class 435, subclass 7.

V. Claims 16 and 17 drawn to a method of detecting the presence of a nucleic acid, classified in class 435, subclass 6.

VI. Claims 19 and 20, drawn to a method of identifying a compound which binds to a polypeptide, classified in class 435, subclass 7.1.

VII. Claim 21, drawn to a method of modulating the activity of a polypeptide, classified in class 514, subclass 2.

VIII. Claim 22, drawn to a method of identifying a compound which modulates the activity of the polypeptide, classified in class 514, subclass 2.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions of Groups I, II and III represent separate and distinct products which are made by materially different methods, and are used in materially different methods which have different modes of operation, different functions and different effects. An isolated nucleic acid of Group I, the polypeptide of Group II and the antibody of Group III are structurally and chemically different from each other. The polynucleotide is made by nucleic acid synthesis while the polypeptide is made by mRNA expression. An isolated nucleic acid of group I or a polypeptide of group II will not encode an antibody of group III, and the antibody of group III cannot be encoded by an isolated nucleic acid of group I or a polypeptide of group II. Furthermore, the polynucleotide can be used for hybridization screening, the polypeptide can be injected into animals to produce antibodies and the antibody can be used in immuno-blot analysis of proteins such as western blots. The examination of all groups would require different searches in U.S. patent shoes and the scientific literature and would require the consideration of different patentability issues. Thus inventions I, II and III are patentably distinct.

The methods of Inventions IV-VIII differ in the method objectives and parameters and different reagents. Group IV a method of detecting the presence of a polypeptide, Group V recites a method of detecting the presence of a nucleic acid, Group VI recites a method of identifying a compound which binds to a polypeptide, Group VII recites a method of modulating the activity of a polypeptide and, Group VIII recites a method of identifying a compound which modulates the activity of the polypeptide. Each invention performs this function using a structurally and functionally different divergent material.

Moreover, the methodology and materials necessary for detecting the presence of a polynucleotide differ from the method of detecting the presence of a polypeptide. Also, the methods of modulating the activity of a polypeptide would be different from that of identifying a compound that modulates the activity of a polypeptide, which in turn both differ from the method of identifying a compound that binds to a polypeptide. Thus groups IV-VIII are distinct as they comprise distinct steps and utilize different products intended towards different end points, which demonstrate that each method has a different mode of operation. Each invention performs the function using structurally and functionally divergent materials. Furthermore, each of the groups employs chemically distinct reagents to accomplish the objectives that comprise methods of detecting the presence of a polynucleotide, polypeptide, identifying a compound that binds to the polypeptide, modulating the activity of the polypeptide and identifying a compound that modulates the activity of the polypeptide. The examination of all groups would require different searches in U.S. patent shoes and the scientific literature and would require the consideration of different patentability issues. Thus, the inventions of groups IV-VIII are separate and distinct in having different method objectives, method steps and parameters and in the reagents used, they are patentably distinct.

Inventions I and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, an isolated nucleic acid of

group I can be used in a materially different process such as in DNA binding assays in addition to the materially different method of group V.

Inventions "II" and "IV, VI-VIII" are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the isolated polypeptide of a group II can be used in a materially different process such as production of antibodies in addition to the materially different method of groups IV-VIII.

Inventions III and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case an antibody of group III can be used in a materially different method such as in pull-down assays or to purify the antigen in addition to the materially different method of group IV.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and different searches in the patent literature and different classification, restriction for examination purposes as indicated is proper.

4. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain

dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

5. Applicant is reminded that upon the cancellation of claims to non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is not longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a protein under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Parithosh K. Tungaturthi whose telephone number is 571-272-8789. The examiner can normally be reached on Monday through Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffery Siew can be reached on (571) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

7. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,

Parithosh K. Tungaturthi, Ph.D.

March 3, 2005

LARRY R. HELMS, PH.D
PRIMARY EXAMINER